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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,810	07/09/2002	Thomas L. McDonald	P04560USO	7193

7590 09/16/2008

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
09/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/069,810	MCDONALD ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-9* is/are rejected.

7)☒ Claim(s) *3,4,10 and 11* is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on March 26, 2008 has been acknowledged and entered.

Claims 1-11 are being examined.

Claims 12-21 are withdrawn.

Claim Objections

Claim 4 is objected to because of the following informalities: "non-infectioe" seems to be misspelled. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting isoforms of SAA protein or mRNA encoding the protein having the Sequence ID Nos. 1, does not reasonably provide enablement for any other isoform of SAA protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass any SAA protein present in the sample would correlate with the inflammatory response. However, the instant specification, page 2, line 11-15, discusses that not all SAA proteins are altered as part of the inflammatory response. (certain SAAs appear to be constitutively expressed or minimally induced in the inflammatory response).

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SAA isoforms for diagnosing mastitis, does not reasonably provide enablement for all SAA isoforms or for all inflammatory responses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass any SAA isoforms or any inflammatory response. However, not all SAA isoforms or inflammatory responses are related to mastitis. In fact, it was not known which SAA isoforms were present in milk in relation to mastitis in an article by Jacobsen et al. (Veterinary Immunology and Immunopathology 104 (2005) 21-31) which is after the filing date of the present application. (see page. 22, col. 1- "but the exact nature of milk SAA protein and the regulation of its synthesis during episodes of mastitis have not yet been elucidated"). Furthermore, inflammatory response would encompass not only mastitis but other conditions such as allergic response, inflammatory breast cancer, etc.

Claims 5-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to describe the one or more inflammatory responsive isoforms of SAA. The specification describes SAA isoforms that relate to mastitis but not isoforms of SAA that relate to other inflammatory responses and as mentioned above, inflammatory response would encompass not only mastitis but other conditions such as allergic response, inflammatory breast cancer, etc.

Maintained Rejection(s)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 6-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 16 of U.S. Patent No. 6,509,444 in view of Hirai et al. (US 5,216, 127).

Patent '444 teaches a method of separating or isolating a serum amyloid A protein (SAA) having sequence ID No. 1, from a colostrum sample of mammal.

However, Patent '444 fails to teach a step of measuring the presence or amount of said SAA protein and performing an ELISA assay.

Hirai teaches performing an ELISA assay to detect SAA protein in any fluid component originated in a living body. (see col. 3, lines 17-20; col. 19, line 50; abstract).

Thus, it would have been obvious to one of ordinary skills in the art to detect or measure the presence or amount of SAA protein in a sample using ELISA assay method as taught by Hirai as a sequential step in the method of Patent '444 to detect the presence or amount of SAA since a detection step must be performed in order to confirm that there is any SAA being separated in the method of patent '444. ELISA is a conventional method of assay or detecting any protein.

Response to Arguments

Applicant's arguments filed March 26, 2008 have been fully considered but they are not persuasive.

Applicants argue that the ODP rejection is improper because the examiner uses the disclosure of patent '444 in view of Hirai to reject the claims of the present invention.

The claims of the present invention are compared to the claims of the primary patent '444. A secondary reference (Hirai) is relied upon for the missing steps and the disclosure of this secondary reference can be used. MPEP 804 fails to exclude the use of the disclosure of a secondary reference/patent. The disclosure of the primary patent '444 is not relied upon in the ODP rejection. Therefore, the OPD is still proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641